

General

Guideline Title

Guideline recommendations and their rationales for the treatment of adult patients. In: Shared decision-making in the appropriate initiation of and withdrawal from dialysis, 2nd edition.

Bibliographic Source(s)

Guideline recommendations and their rationales for the treatment of adult patients. In: Renal Physicians Association (RPA). Shared decision-making in the appropriate initiation of withdrawal from dialysis. 2nd ed. Rockville (MD): Renal Physicians Association (RPA); 2010 Oct. p. 39-92. [370 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Society of Nephrology, Renal Physicians Association. Clinical practice guideline on shared decision-making in the appropriate initiation of and withdrawal from dialysis. Washington (DC): Renal Physicians Association; 2000 Jan. 124 p. [302 references]

Galla JH. Clinical practice guideline on shared decision-making in the appropriate initiation of and withdrawal from dialysis. Renal Physicians Association and the American Society of Nephrology. J Am Soc Nephrol 2000 Jul;11(7):1340-2. [302 references]

The Renal Physicians Association reaffirmed the currency of this guideline in 2013.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Establishing a Shared Decision-Making Relationship

Recommendation No 1: Develop a Physician-Patient Relationship for Shared Decision-Making

Shared decision-making is the recognized preferred model for medical decision-making because it addresses the ethical need to fully inform patients about the risks and benefits of treatments, as well as the need to ensure that patients' values and preferences play a prominent role. Because of the number and complexity of decisions involved in treating kidney failure, a shared decision-making relationship is particularly important for patients with acute kidney injury (AKI); stage 4 and 5 chronic kidney disease (CKD); and stage 5 CKD requiring dialysis end-stage renal disease (ESRD). Participants in shared decision-making should involve at a minimum the patient and the physician. In addition, patients should identify and include a person who could serve as their decision maker in the event they lose decision-making capacity. If a patient lacks

decision-making capacity, decisions should involve the person legally authorized to make health care decisions on behalf of the incapacitated patient. This person is often (though not always) a family member and will be called "the legal agent" in the remainder of this document (see Section 10: Glossary in the full version of the current guideline for a full description). With the patient's consent, shared decision-making may include family members or friends and other members of the health care team.

Informing Patients

Recommendation No 2: Fully Inform AKI, Stage 4 and 5 CKD, and ESRD Patients about Their Diagnosis, Prognosis, and All Treatment Options

In the setting of critical illness many patients with CKD will require urgent dialysis and the vast majority of patients with AKI will have multiple medical problems, in addition to kidney failure. The concept of shared decision making necessitates a multidisciplinary approach including nephrologists, intensivists, and others as appropriate and decisions about acute renal replacement therapy should be made in the context of other life-sustaining treatments. For example, a decision to withhold dialysis in a patient agreeing to and receiving multiple other forms of life sustaining therapy could represent discordant treatment in the same way that offering dialysis to a patient who has decided to forgo other forms of life-sustaining therapy might be inappropriate. Intensive care physicians need to be included in shared decision making for kidney patients in the intensive care unit (ICU).

For ESRD patients, these options in shared decision-making include: 1) available dialysis modalities and kidney transplantation if applicable; 2) not starting dialysis and continuing medical management; 3) a time limited trial of dialysis, and 4) stopping dialysis and receiving end-of-life care. Choices among options should be made by patients or, if patients lack decision-making capacity, their designated legal agents. Their decisions should be informed and voluntary. The renal care team, in conjunction with the primary care physician, should insure that the patient or legal agent understands the benefits and burdens of dialysis and the consequences of not starting or stopping dialysis. Research studies have identified a population of chronic kidney disease patients for whom the prognosis is particularly poor. This population has been found to include patients with two or more of the following characteristics: 1) elderly (defined by research studies identifying poor outcomes in patients who are age 75 years and older); 2) patients with high comorbidity scores (e.g., modified Charlson Comorbidity Index score of 8 or greater); 3) marked functional impairment (e.g., Karnofsky Performance Status Scale score of less than 40); and 4) severe chronic malnutrition (e.g., serum albumin level less than 2.5 g/dL using the bromcresol green method). Patients in this population should be informed that dialysis may not confer a survival advantage or improve functional status over medical management without dialysis and that dialysis entails significant burdens that may detract from their quality of life.

Box 1. Suggested Steps for Implementing Recommendation Nos. 1 and 2

- Identify provider(s) who will coordinate communication with the patient or legal agent and family (e.g., nephrologist in conjunction with the primary care provider for ESRD patients or intensivists for AKI).
- Assess patient decision-making capacity and whether it is diminished by major depression, encephalopathy, or other disorder (see Tool 4 in Section 9: Toolkit for helpful instruments in the full version of the current guideline). Obtain psychiatric and/or neurological consultation as appropriate, and institute treatment for conditions impairing decision-making capacity.
- Communicate diagnosis to patient (or legal agent) and family (if the patient agrees).
- Discuss prognosis based upon patient's medical condition, comorbidities, functional status, and age (see Tools 6-1 to 6-3 in Section 9: Toolkit for tools for assessing functional status and quality of life, and estimating prognosis in the full version of the current guideline).
- Identify the patient's wishes.
- Communicate options, taking advantage of educational resources, such as other patients or videotapes and brochures.
- If the patient wants to forgo dialysis, determine why.
 - Are the patient's perceptions about dialysis accurate? Does the patient know what to expect if dialysis is not started or is discontinued?
 - Does the patient really mean what he/she says or is the decision to refuse or stop dialysis made to get attention, help, or control?
 - Are there changes that might improve quality of life and would the patient be willing to start or continue dialysis while the factors responsible for the patient's request are addressed?
 - Are there persons (e.g., social worker, chaplain) with whom the patient would be willing to discuss the decision?

(Also, see Tool 8-2 in Section 9 in the full version of the current guideline: Toolkit for NKF checklist on withdrawing dialysis.)

Reach decision based on medical indications and national's preferences

- reach decision based on medical indications and patients preferences.
- Encourage patient to discuss end-of-life issues with others such as family, friends, or spiritual advisors (see Tool 5-1 in Section 9 in the full version of the current guideline: Toolkit for helpful questions to use).
- Refer for palliative care and hospice as appropriate.

Recommendation No. 3: Give All Patients with AKI, Stage 5 CKD, or ESRD an Estimate of Prognosis Specific to Their Overall Condition

To facilitate informed decisions about starting dialysis for AKI, stage 5 CKD, or ESRD, all patients should have their prognosis estimated and discussed, with the realization that the ability to predict survival in the individual patient is limited. Depending on the setting, a primary care physician, intensivist, or nephrologist who is familiar with estimating and communicating prognosis should conduct these discussions (see Recommendation No. 10 for communication strategies). For patients with ESRD, the "surprise" question "Would I be surprised if this patient died in the next year?" can be used together with known risk factors for poor prognosis: age, comorbidities, severe malnutrition, and poor functional status. For patients with stage 5 CKD pre-dialysis, the estimate of prognosis should be discussed with the patient or legal agent, patient's family, and among the medical team members to develop a consensus on the goals of care and whether dialysis or active medical management without dialysis should be used to best achieve these goals. These discussions should occur as early as possible in the course of the patient's kidney disease and continue as the kidney disease progresses. For ESRD patients on dialysis who experience major complications that may substantially reduce survival or quality of life, it is appropriate to reassess treatment goals, including consideration of withdrawal from dialysis.

Box 2. Suggested Steps for Implementing Recommendation No. 3

- For ESRD patients, estimate prognosis based upon patient's age, functional status, medical condition, including comorbidity and recent sentinel events, and the "surprise" question. The website http://touchcalc.com/calculators/sq provides a calculator for use of the surprise question response and other variables to estimate prognosis in dialysis patients. The same degree of precision does not exist for tools that estimate prognosis for patients with AKI.
- Present the prognosis in a manner that is considerate of the patient's emotional condition. Balance the patient's desire for quality and
 quantity of life and provide reassurance that the physician has kept the patient's best interest in mind. With the patient's permission,
 strongly encourage the patient's legal agent/family to participate in the discussion of prognosis and treatment options. See
 Recommendation No. 10 for suggested approaches to discussing prognosis, treatment options, and goals of care with AKI, CKD, and
 ESRD patients.
- Identify patient's wishes and goals for treatment at onset of dialysis and again after any irreversible change in medical condition.
- For ESRD patients, reassess and communicate prognosis on at least an annual basis, and more often as indicated by any major change in status.
- For CKD and ESRD patients, during each annual Comprehensive Assessment and Plan of Care discussion, communicate appropriate options based on the patient's condition, prognosis, and goals for care. Regardless of choice, palliative care should be offered for pain and symptom management and advance care planning. Hospice referral is appropriate for ESRD patients stopping dialysis.
- Provide recommendation to withhold/stop dialysis in patients who are not likely to benefit.
- If conflicts arise in shared decision-making, consider palliative care or ethics consultation (see Recommendation No. 8).

Facilitating Advance Care Planning

Recommendation No. 4: Institute Advance Care Planning

The purpose of advance care planning is to help the patient understand his/her condition, identify his/her goals for care, and prepare for the decisions that may have to be made as the condition progresses over time. For chronic dialysis patients, the interdisciplinary renal care team should encourage patient-family discussion and advance care planning and include advance care planning in the overall plan of care for each individual patient. The renal care team should designate a person to be primarily responsible for ensuring that advance care planning is offered to each patient. Patients with decision-making capacity should be strongly encouraged to talk to their legal agents while they still have capacity to ensure that the legal agent knows the patient's wishes and agrees to make decisions according to these wishes.

The renal care team should attempt to obtain written advance directives from all dialysis patients. Where legally accepted, Physician Orders for Life-Sustaining Treatment (POLST) or similar state-specific forms, also should be completed as part of the advance care planning process. At a minimum, each dialysis patient should be asked to designate a legal agent in a state-specific advance directive. Advance directives should be honored by dialysis centers, nephrologists, and other nephrology clinicians except possibly in situations in which the advance directive requests treatment contrary to the standard of care (see Recommendation No. 8 on conflict resolution).

Box 3. Suggested Steps for Implementing Recommendation No. 4

- Assess decision-making capacity (see Tool 4-1 in Section 9: Toolkit in the full version of the current guideline).
- Include advance care planning in the Comprehensive Assessment and Plan of Care for each individual patient.
- Inform dialysis patient of his/her right to complete an advance directive and of the dialysis facility's policy with regard to advance directives as required by the 2008 Conditions for Coverage.
- Encourage patient-centered advance care planning among patients and families; raise the issue of advance care planning with each
 patient at the initiation of dialysis (earlier is preferred) and on at least a yearly basis. Hospitalizations and/or significant changes in
 medical, physical, or functional status should prompt reconsideration of advance care planning.
- Discuss advance care planning by asking:
 - If you become unable to make decisions for yourself, whom do you want to make decisions for you?
 - If you had to choose between being kept alive as long as possible regardless of personal suffering or living a shorter time to avoid suffering which would you choose?
 - Under what circumstances, if any, would you want to stop dialysis?
 - If your heart stops beating or you stop breathing, would you want to allow a natural death?
 - Under what circumstances, if any, would you not want to be kept alive with medical means such as cardiopulmonary resuscitation, a feeding tube, or mechanical ventilation?
 - Where do you prefer to die and who do you wish to be with you when you die?
- Determine whether the patient has an appointed legal agent through a written advance directive.
- If the patient lacks decision-making capacity and has not completed an advance directive, arrange for or initiate the process for appointing a surrogate according to state law.
- Encourage patients to be specific about their preferences with legal agent, family, friends, and providers.
- Document provider's discussion and understanding of patient's preferences, show the patient the documentation, and offer to assist the patient in documenting the patient's agreement or modification of the documentation. Where available, complete a Physician Orders for Life-Sustaining Treatment (POLST) or similar form to translate patients' wishes into medical orders (see www.polst.org
- Place a copy of advance directives, DNR order card, and/or POLST form in multiple medical records as appropriate, including dialysis facility, commonly attended clinics, hospital, nursing home, and home.
- Encourage the patient, family and/or legal agent to carry a current copy of the patient's advance directive, do not resuscitate order card, and/or POLST form whenever traveling or being admitted for overnight medical care.

Box 4. Desired Outcomes for Advance Care Planning for CKD and ESRD Patient

- Enhance patient and family understanding about their illness and end-of-life issues, including prognosis and likely outcomes of alternative plans of care.
- Define the particular patient's key priorities in end-of-life care and develop a care plan that address these issues and identifies the patient's overall goals of care.
- Enhance patient autonomy by shaping future clinical care to fit the patients preferences and values.

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- Improve the process of health care decision-making generally, including 1) patient and family satisfaction with the advance care planning process; 2) health care provider understanding of advance care planning and advance directives; and 3) provider comfort in participating in advance care planning.
- Help patients find hope and meaning in life and achieve a sense of spiritual peace.
- Explore ways to ease the emotional and financial burdens borne by patients and families.
- Strengthen relationships with loved ones.
- Complete written advance directives, particularly those identifying a legal agent, do not resuscitate documents, and POLST documents where available.
- Honor advance directives, do not resuscitate orders, and POLST orders at the end of life.

Making a Decision to Not Initiate or to Discontinue Dialysis

Recommendation No. 5*: If Appropriate, Forgo (Withhold Initiation or Withdraw Ongoing) Dialysis for Patients with AKI, CKD, or ESRD in Certain, Well-defined Situations

These situations include the following:

- Patients with decision-making capacity, who being fully informed and making voluntary choices, refuse dialysis or request that dialysis be
 discontinued.
- Patients who no longer possess decision making capacity who have previously indicated refusal of dialysis in an oral or written advance directive
- Patients who no longer possess decision making capacity and whose properly appointed legal agents/surrogates refuse dialysis or request that it be discontinued.
- Patients with irreversible, profound neurological impairment such that they lack signs of thought, sensation, purposeful behavior, and awareness of self and environment.

*Medical management incorporating palliative care is an integral part of the decision to forgo dialysis in AKI, CKD, or ESRD, and attention to patient comfort and quality of life while dying should be addressed directly or managed by palliative care consultation and referral to a hospice program (see Recommendation No. 9 on palliative care services).

Recommendation No. 6: Consider Forgoing Dialysis for AKI, CKD, or ESRD Patients Who Have a Very Poor Prognosis or for Whom Dialysis Cannot Be Provided Safely

Included in these categories of patients are the following:

- Those whose medical condition precludes the technical process of dialysis because the patient is unable to cooperate (e.g., advanced dementia patient who pulls out dialysis needles) or because the patient's condition is too unstable (e.g., profound hypotension).
- Those who have a terminal illness from non-renal causes (acknowledging that some in this condition may perceive benefit from and choose to undergo dialysis).
- Those with stage 5 CKD older than age 75 years who meet two or more of the following statistically significant very poor prognosis criteria (see Recommendations No. 2 and 3): 1) clinicians' response of "No, I would not be surprised" to the surprise question; 2) high comorbidity score; 3) significantly impaired functional status (e.g., Karnofsky Performance Status score less than 40); and 4) severe chronic malnutrition (i.e., serum albumin less than 2.5 g/dL using the bromcresol green method).

Resolving Conflicts about What Dialysis Decisions to Make

Recommendation No. 7: Consider a Time-Limited Trial of Dialysis for Patients Requiring Dialysis, But Who Have an Uncertain Prognosis, or for Whom a Consensus Cannot Be Reached about Providing Dialysis

If a time-limited trial of dialysis is conducted, the nephrologist, the patient, the patient's legal agent, and the patient's family (with the patient's permission to participate in decision-making) should agree in advance on the length of the trial and parameters to be assessed during and at the completion of the time limited trial to determine whether dialysis has benefited the patient and whether dialysis should be continued.

Recommendation No. 8: Establish a Systematic Due Process Approach for Conflict Resolution if There Is Disagreement about What Decision Should Be Made with Regard to Dialysis

Conflicts may occur between the patient/legal agent and the renal care team about whether dialysis will benefit the patient. Conflicts also may occur within the renal care team or between the renal care team and other health care providers. In talking with patients/legal agents, the nephrologist should try to understand their views, provide data to support his/her recommendation, and correct misunderstandings. In the process of shared decision-making, the following potential sources of conflict have been recognized: 1) miscommunication or misunderstanding about prognosis; 2) intrapersonal or interpersonal issues; or 3) special values. If dialysis is indicated emergently, it should be provided while pursuing conflict resolution, provided the patient or legal agent requests it.

Box 5. Suggested Steps for Implementing Recommendation No. 8

Engage in extended conversation for either request for dialysis when not recommended or refusal of dialysis when recommended:

- Why does the patient or legal agent desire dialysis when it is not recommended by the renal care team?
- Does the nephrologist misunderstand the patient's or legal agent's reasons for requesting dialysis?
- Does the patient or legal agent misunderstand the diagnosis, prognosis, and treatment alternatives and why dialysis is not recommended?
- Why does the patient or legal agent refuse dialysis when it is recommended by the renal care team?
- Is the patient's refusal of recommended dialysis based on an accurate understanding of the likely benefits of dialysis?
- Is the patient's refusal of recommended dialysis consistent with the patient's values and goals?
- Does the nephrologist understand the psychosocial, cultural, or spiritual concerns and values the patient or legal agent has?
- Has the nephrologist consulted a psychologist, social worker, or chaplain for assistance in fully understanding the concerns of the patient or legal agent/family? Have strategies in the Decreasing Provider Patient Conflict project been used as appropriate?

For circumstances in which the patient/legal agent requests dialysis when it is not recommended, the following process may be helpful to resolve the conflict:

- Consult with other physicians
 - Do other physicians agree or disagree with the attending physician's recommendation to withhold or withdraw dialysis?
 - Is the request for dialysis by the patient or legal agent medically appropriate?
- Consult with an ethics committee or ethics consultants
 - Has the patient or legal agent been informed that the purpose of the ethics consult is clarify issues of disagreement, and ideally, to enable resolution?
 - Has the patient or legal agent met with the ethics committee or ethics consultants to explain their perspective and reasoning behind their request for dialysis?
 - Can the ethics committee identify the reasons why the patient or legal agent is resistant to the physician's recommendation to forgo dialysis?
 - Can the ethics committee identify the reasons why the health care provider is resistant to the patient's or legal agent's desire to begin or continue dialysis?
 - Has the ethics committee explained in understandable terms to the patient or legal agent its conclusions and the reasoning behind them?
 - Can the impasse be resolved with accommodation, negotiation, mediation, or a time-limited trial of dialysis?

Document

- The physician must document the medical facts and his/her reasons for the recommendation to forgo dialysis and the decision not to agree to the request by the patient or legal agent.
- The consultants also should document their assessment of the patient's diagnosis, prognosis, and their recommendations in the chart.
- Attempt to transfer the patient's care
 - If reconciliation is not achieved through the above procedure and the physician in good conscience cannot agree to the patient or legal agent's request, the physician may ethically and legally attempt to transfer the care of the patient to another physician.

- Another physician and/or institution may not be found who is willing to accept the patient under the terms of the family's request.
 Physicians and institutions that refuse to accept the patient in transfer and their reasons should also be documented in the medical record.
- Consider consultation with a mediator, extramural ethics committee, or the ESRD Network in the region.
- Request regional ESRD network to assist with arranging dialysis.
- Notify the patient, legal agent, and/or family
 - If no other physician or institution can be found in the community or region by the treating nephrologist to provide dialysis as requested, the physician may inform the patient or legal agent that the nephrologist will cancel the patient's dialysis orders and the dialysis center will no longer provide dialysis to the patient. The nephrologist is obligated to give the patient sufficient advance notice and the names and addresses of other nephrologists and other dialysis facilities in the area.
- Communicate options
 - The options of filing a grievance with the ESRD network (chronic patients only) or seeking legal or regulatory recourse by the patient or legal agent should be communicated.

Providing Effective Palliative Care

Recommendation No. 9: To Improve Patient-Centered Outcomes, Offer Palliative Care Services and Interventions to All AKI, CKD, and ESRD Patients Who Suffer from Burdens of Their Disease

Palliative care services are appropriate for people who chose to undergo or remain on dialysis and for those who choose not to start or to discontinue dialysis. With the patient's consent, a multi-professional team with expertise in renal palliative care, including nephrology professionals, family or community-based professionals, and specialist hospice or palliative care providers, should be involved in managing the physical, psychological, social, and spiritual aspects of treatment for these patients, including end-of life care. Physical and psychological symptoms should be routinely and regularly assessed and actively managed. The professionals providing treatment should be trained in assessing and managing symptoms and in advanced communication skills. Patients should be offered the option of dying where they prefer, including at home with hospice care, provided there is sufficient and appropriate support to enable this option. Support also should be offered to patients' families, including bereavement support where appropriate. Dialysis patients for whom the goals of care are primarily comfort should have quality measures distinct from patients for whom the goals are aggressive therapy with optimization of functional capacity.

Box 6: Recommendations for End-of-life Care Practices in Chronic Kidney Disease

- 1. Identify patients who would benefit from palliative care interventions.
 - a. Those who are being managed medically, i.e., a GFR ≤15ml/min/1.73m² with no dialysis.
 - b. High risk of death within the next year. Consider using an integrated prognostic model and/or the surprise question, "Would I be surprised if this patient died in the next year?"
- 2. Screen for and manage pain and other physical symptoms routinely.
 - a. A simple tool such as the Edmonton Symptom Assessment Scale (ESAS) is appropriate and has been validated in CKD.
- 3. Screen for and manage emotional, psychosocial and spiritual distress; refer to allied health professionals as appropriate.
 - a. The ESAS is also appropriate for screening for anxiety and depression.
 - b. A simple question such as "Do you have any spiritual needs or concerns that your health care providers may help address?" may be appropriate for screening for spiritual distress.
- 4. Assess patients' desire for prognostic information.
- 5. Enhance pre-dialysis education
 - a. Educate regarding active medical management without dialysis option as appropriate.
 - b. Education should include available palliative care and hospice services.
- 6. Provide routine advance care planning (ACP) as described in Recommendation No. 5
 - a. Ensure patients and families are aware of the relevance of these discussions (i.e., have an understanding of their overall health state and prognosis).
 - b. Consider initiating ACP at the time that patients are being educated with respect to renal replacement options.

- Include discussions of patients' goals of care, health states that the patient would no longer want dialysis, and preferred location of death.
- d. Establish a surrogate decision-maker.
- e. Ensure that family and other important people (as identified by the patient) are present for these discussions, especially the surrogate decision-maker.
- 7. Increase access to specialist palliative care including hospice
- 8. Develop relationships with hospice providers that focus on transition of care from dialysis to hospice, bridging patients into hospice by decreasing frequency of dialysis treatments, and having the patient be in control of when they are ready to stop palliative dialysis.
- 9. Provide bereavement support to patients' families where necessary.
- 10. Incorporate palliative care training for all nephrology fellows with an emphasis on symptom management, advance care planning, and communication about prognosis and treatment options.

Recommendation No. 10: Use a Systematic Approach to Communicate about Diagnosis, Prognosis, Treatment Options, and Goals of Care

Good communication improves patients' adjustment to illness, increases adherence to treatment, and results in higher patient and family satisfaction with care. Patients appreciate sensitive delivery of information about their prognosis and the ability to balance reality while maintaining hope. In communicating with patients, the critical task for clinicians is to integrate complicated biomedical facts and conditions with emotional, social, and spiritual realities that are equally complex but not well described in the language of medicine. This information must be communicated in a way that patients, legal agents, and families can understand and use to reach informed decisions about dialysis and transplantation options. Patients' decisions should be based on an accurate understanding of their condition and the pros and cons of treatment options. To facilitate effective communication, reliance upon a multidisciplinary approach including nephrologists, intensivists, and others as appropriate is warranted. Decisions about acute renal replacement therapy in AKI should be made in the context of other life-sustaining treatments. Intensive care physicians should be included in shared decision-making for kidney patients in the ICU to facilitate discussions on global disease or injury prognosis. Fellowship programs should incorporate training to help nephrologists develop effective, empathetic communication skills, which are essential in caring for this patient population.

Box 7. A Six-Step Approach to Talking about Serious Illness

- 1. Set up the conversation. This includes making the environment private and quiet. Also have a nurse or social worker available for further discussion after you leave.
- 2. Assess the patient's perception. Asking what the patient understands or expects can be helpful in determining how you approach and plan the conversation.
- 3. Ask for an invitation to talk about the news. By asking the patient if you can discuss the news gives them some control and emphasizes your goal to work cooperatively.
- 4. *Disclose the news straightforwardly to improve the patient's knowledge*. It is best to start with a warning statement to let the patient brace themselves for bad news. The news should be straightforward and be delivered in comprehensible language.
- 5. Respond to the patient's emotions. The physician must be aware of the patient's emotion and be able to respond to it in an empathic way.
- 6. Summarize the plan. At the close of the visit, the physician should summarize what has been discussed and describe the next steps the patient will need to take.

Clinical Algorithm(s)

The algorithm, Systematic Approach to Resolving Conflict between Patient and Kidney Care Team, is provided in the full version of the current guideline.

Scope

Disease/Condition(s)

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|---|-------|--------|---|-----|
| • | Acute | kidney | m | urv |
| | | | | |

- Acute renal failure
- Stage 4 or 5 chronic kidney disease
- End-stage renal disease

| Guideline Category | | |
|--------------------|--|--|
| Counseling | | |
| Evaluation | | |
| Management | | |
| Risk Assessment | | |
| Treatment | | |
| | | |
| Clinical Specialty | | |
| Critical Care | | |
| Family Practice | | |
| Internal Medicine | | |

Nursing

Nephrology

Nutrition

Psychology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dietitians

Health Care Providers

Hospitals

Nurses

Other

Patients

Physician Assistants

Physicians

Guideline Objective(s)

- To provide clinicians, patients, and families with 1) the most current evidence about the benefits and burdens of dialysis for patients with
 diverse conditions, 2) recommendations for quality in decision-making and treatment of patients with acute kidney injury (AKI), chronic
 kidney disease (CKD), and end-stage renal disease (ESRD), and 3) practical strategies to help clinicians implement the guideline
 recommendations
- To provide systematically developed statements to assist practitioner and patient decisions about appropriate healthcare (in this case dialysis) for specific clinical circumstances
- To synthesize available research evidence on patients with AKI, CKD, and ESRD as a basis for making recommendations about starting, withholding, continuing, and withdrawing dialysis
- To enhance understanding of the principles and processes useful for and involved in making decisions to withhold or withdraw dialysis
- To promote ethically as well as medically sound decision-making in individual cases
- To recommend tools that can be used to promote shared decision-making in the care of patients with AKI, CKD, or ESRD
- To offer a publicly understandable and acceptable ethical framework for shared decision-making among health care providers, patients, and their families

Target Population

Adult patients with acute kidney injury, stage 4 or 5 chronic kidney disease, or end-stage renal disease

Interventions and Practices Considered

- 1. Shared decision-making in the appropriate initiation of and withdrawal from dialysis and developing a physician-patient relationship for shared decision-making
- 2. Fully informing acute kidney injury (AKI), stage 4 and 5 chronic kidney disease (CKD), and end-stage renal disease (ESRD) patients about their diagnosis, prognosis, and all treatment options.
- 3. Estimating prognosis
- 4. Advance care planning
- 5. Withholding or withdrawing dialysis in certain well-defined situations
- 6. Forgoing dialysis in AKI, CKD, or ESRD patients
- 7. Time-limited trial of dialysis
- 8. Conflict resolution
- 9. Palliative care
- 10. Systematic approach to communicating about diagnosis, prognosis, treatment options, and goals of care

Major Outcomes Considered

- Prevalence of withdrawal from dialysis
- · Recovery of renal function
- Morbidity
- Mortality
- Quality of life
- Charlson Comorbidity Index score
- Karnofsky Performance Status Scale score
- Complications of dialysis
- Cost
- Referral to palliative care
- Referral to hospice

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Original Guideline

Search Strategy for Relevant Research Evidence

Pertinent English language literature published from 1985 to December 1998 was identified from the following:

- Electronic databases (MEDLINE, CINAHL, HealthStar, PsycINFO, and EMBASE)
- References from articles
- Experts
- Hand searches of eight medical and nephrology journals of issues covering the last six months of 1998

Research evidence based on data collected before 1985 was not sought because marked technological advances in dialysis delivery have occurred since that time. Preliminary searches of electronic databases using specific search terms, such as dialysis, acute renal failure or end-stage renal disease and withdrawal, preferences, prognosis, or quality of life, did not adequately capture the array of literature of interest to the Working Group. Thus a very broad search strategy was used; it only included terms for dialysis, end-stage renal disease, and acute renal failure, and it excluded unpublished studies, case reports, editorials, and letters.

Selection of Relevant Research Evidence

Selection criteria guided the selection of several types of information that were deemed relevant to the key questions (see Table 2 in the full version of the current guideline). For information about prognosis in patients with end-stage renal disease (ESRD), large retrospective or prospective cohort studies with at least 100 patients that examined multivariate predictors of mortality or morbidity were selected. For information about prognosis in patients with acute kidney injury (AKI), smaller retrospective or prospective studies involving at least 20 dialysis patients and reporting mortality outcomes were used. Information relevant to who gets referred for dialysis and when, feasibility, withdrawal frequencies and reasons, patient preferences, shared decision-making, advance directives, and quality of life assessments was taken from descriptive surveys, case-control studies, cohort studies, or randomized trials with at least 20 patients who were receiving or awaiting dialysis. Research evidence from Asian and developing countries was not used because differences in access to dialysis, patients' values and preferences, and decision-making processes were considered likely to limit generalizability and applicability to patients in the United States.

Abstracts of the 5,283 potentially eligible records were screened by at least two persons to identify those meeting selection criteria. Of these, 4,718 were excluded, usually because they addressed short-term complications, physiologic parameters, management or adequacy of dialysis, or because they did not contain primary data. The full texts of the remaining 565 articles were retrieved and reviewed by at least two persons to ascertain final eligibility. Of 329 articles meeting criteria, 29 contained information from the same study populations leaving 300 unique studies for review. A physician with clinical and methodological expertise resolved disagreements about eligibility criteria.

Second Edition (2010)

The Renal Physician Association (RPA) sponsored the development of the second edition of this guideline using essentially the same methodology as the original guideline. In late 2002, the RPA considered doing a revision but found insufficient new information to warrant it at that time. The RPA revisited the issue more recently, found sufficient new evidence, and the RPA Quality, Safety, and Accountability Committee oversaw this guideline revision. For this revision, pertinent adult and pediatric English language literature published from January 2003 to October 2009 was identified from the following:

- PubMed
- · References from articles

- Experts
- Hand searches of medical and nephrology journals

In addition to the search terms used in the original guideline development, palliative care and end-of-life care were also included. Figure 5 in the full version of the current guideline includes a diagram of the article selection process for the guideline revision.

2013 Reaffirmation

In December 2013 a systematic literature review of the literature on which the RPA guideline was based was performed by the Kidney Disease: Improving Global Outcomes (KDIGO) participants in the KDIGO Controversies Conference on Supportive/Palliative Care in Chronic Kidney Disease, many of whom helped to develop the 2010 guideline.

For this systematic literature review, pertinent adult English language literature published from October 1, 2009 through December 5, 2013 was identified from the following databases: PubMed, Scopus, Google Scholar, and ScienceDirect; references from articles; national and international experts; and hand searches of medical and nephrology journals.

In 2013 the search terms used included those in the first and second edition of the clinical practice guideline, and the search was supplemented with the additional following terms: dialysis or chronic kidney disease AND prognosis, pain, symptoms, advance care planning, shared decision-making, palliative care, end-of-life care, conservative management, initiation, withholding, withdrawal, cost effectiveness, ethics, health economics, or costs. Also searched were combinations of "education," "shared decision-making," "dialysis," "withholding," "withdrawing," "modality," "palliative care," "supportive care" AND "choice," "pre-dialysis" AND "withholding," "dialysis" AND "withdrawal," "religion," "culture," "ethnicity," "end of life," "palliative care," dialysis" AND "cost-effectiveness," "palliative OR hospice" AND "cost-effectiveness," "ethics in dialysis," "shared decision making," "time limited trial," "palliative care in nephrology."

Articles identified using the search terms noted above were included if, after the review of the abstract, the article was deemed relevant to the content area of the workgroup.

Number of Source Documents

Original Guideline

300 unique studies met the selection criteria.

Second Edition (2010)

385 new studies were included in the evidence base.

2013 Reaffirmation

The participants did not report the number of articles that were identified, but they did prepare a list of studies included in their literature survey summary. The studies identified by workgroup are below.

- 1. Pain and Other Symptoms: 702 articles
- 2. Prognosis: 47 articles
- 3. Advance Care Planning and Shared Decision-Making: 185 articles
- 4. Initiation, Withholding, and Withdrawal of Dialysis: 30 articles
- 5. Comprehensive Conservative Management: 98 articles

Total articles read and synthesized for 2013 systematic literature review: 1,062

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence for Different Types of Studies

Criteria for grading studies addressing therapy, prevention, and prognosis were adapted from the Centre for Evidence-based Medicine at Oxford's criteria for rating evidence. Criteria for rating observational evidence were developed by the San Antonio Evidence-based Practice Center.

Observational/Descriptive Evidence

- A. Multiple large studies or single nationally representative study with >80% response rate(s).
- B. Multiple small studies from diverse populations with response rates of 60% to 80%.
- C. Few studies, selective samples, or low response rates.

Therapy/Prevention

- A. Multiple randomized controlled trials or single trial with narrow confidence interval.
- B. Cohort study or low quality randomized trial (e.g., <80% follow-up, small sample size, unequal co-interventions or biased outcome assessment).
- C. Case-control studies.

Prognosis

- A. Inception cohort studies (multiple or single large representative study) with >80% follow-up, and/or models from such studies validated with test sets
- B. Retrospective cohort study, prevalent cohort study, or follow-up of untreated control patients in a randomized trial, or multiple studies find similar risk ratios for a given risk factor.
- C. Case-control studies or biased cohort studies with inadequate control for confounding variables, biased outcome, or biased exposure ascertainment.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Data Abstraction Process

Standard forms were used to abstract data from each study. Such data included information about study purposes and designs, participant descriptors, methodological characteristics, outcome measures, and results. Items related to the internal validity of studies that were assessed included: selective recruitment of study participants, problematic outcome assessment, high drop-out or nonresponse rates, discordance with current standards of care, confounding cointerventions, inappropriate analysis, and inadequate power.

Thirty-five individuals participated in the abstraction process. To aid standardization of abstraction, teams of abstractors were assigned articles related to specific thematic areas, such as prognosis of acute kidney injury (AKI), prognosis of end-stage renal disease (ESRD), feasibility of dialysis, referral of patients for dialysis, quality of life of dialysis patients, withdrawal of dialysis, preferences, decision-making capacity, and advance directives. Working Group members were assigned to thematic teams based upon their clinical or methodological expertise. Disagreements between abstractors were resolved by the Work Group chair.

Levels of Evidence

| The criteria that were used to rate the quality of evidence are described in Table 3 of the full version of the current guideline. Criteria for grading | 5 |
|---|----|
| evidence addressing therapy, prevention, and prognosis were adapted from those of the Centre for Evidence-based Medicine at Oxford | |
| (www.cebm.net/index.aspx?o=1025). Criteria for rating observational evidence were developed by the San Antonio | |
| Evidence-based Practice Center. The text in the rationales for each recommendation gives the ranking for the body of research evidence relevant | nt |
| to individual statements. When multiple relevant studies of varying quality were available, the evidence was rated according to the highest ranked | 1 |
| study. Meta-analysis was not used to quantitatively summarize study data because of marked heterogeneity in study designs and study populatio | ns |
| and because quantitative techniques for summarizing prognostic studies that use multivariate analysis are not well developed | |

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Expert Consensus (Nominal Group Technique)

Description of Methods Used to Formulate the Recommendations

2010 Guideline

In developing the original guideline, the Renal Physicians Association (RPA) and the American Society of Nephrology (ASN) selected the topic, committed resources towards its development, and organized the creation of a multidisciplinary Working Group to oversee the development process. The RPA and ASN appointed a steering panel that was charged with framing the scope of the guideline, identifying the relevant stakeholders and groups that should be represented on the multidisciplinary Working Group, and outlining the requirements for technical and administrative contractor support to develop the guideline. The panel selected staff from the San Antonio Evidence-Based Practice Center (EPC) and VA Cochrane Center to provide such support using methodology adapted from the Agency for Health Care Policy and Research (AHCPR) guideline process and outlined in the American Medical Association's Attributes for Clinical Practice Guideline Development document. The RPA and ASN announced the guideline process in mid-1998 and invited interested parties to share pertinent ideas and comments with members of the Working Group and the San Antonio EPC/VA Cochrane Center.

The Working Group formulated specific guideline recommendations, taking into account several parameters: 1) ethical principles; 2) legal statutes; 3) shared decision-making; 4) the amount, type, quality, and consistency of supporting research evidence; and 5) the anticipated feasibility of implementation. There was considerable heterogeneity in the types of questions that the Working Group posed and in the types of research studies that were deemed relevant to those questions. Most often, relevant studies were prognostic cohort studies or observational studies (e.g., surveys, case series) that provided descriptive information. In a few instances, randomized controlled trial evidence was considered relevant.

Two analytic frameworks, one for acute kidney injury (AKI) and one for end-stage renal disease (ESRD), were developed to provide a conceptual framework for decisions about withholding or withdrawing dialysis. The models are presented in Figures 3 and 4 in the full version of the current guideline. They depict a dynamic chronological sequence of decision-making that is informed by multiple factors, such as patient preferences, prognosis, and feasibility of dialysis.

The Working Group proposed and prioritized key questions related to the models using a combined nominal and modified Delphi process. Questions specified information that was either desirable or necessary to make informed and ethical decisions about withholding or withdrawing dialysis. Such questions were categorized as directly informative to the evidence model or as background and contextual in nature. These key questions guided analysis of the evidence. The specific evidence questions for decision-making about dialysis in AKI and ESRD are listed in the full version of the current guideline.

The Working Group was provided with background information regarding principles of ethical decision-making. They were also given information regarding guideline development processes and desirable attributes of performance measures that may be used to help insure guideline implementation. They were provided with evidence tables that summarized the available research evidence relevant to the analytic framework questions. Based on these materials, teams within the Working Group formulated draft guideline recommendations. A general consensus process involving the entire group was used to reach agreement on final recommendations.

2013 Reaffirmation

The Working Group affirmed the validity of the present guideline and concluded that there was not a need to revise the guideline at this time.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer review of the guideline was solicited at multiple points. First, for the adult patient recommendations and rationales, peer review of the revisions suggested by each workgroup was performed within the workgroups. Second, the seven workgroup chairs for the adult recommendations reviewed all seven workgroups' suggested changes. Each workgroup chair had previously been involved only in the literature review and revision of his or her assigned original guideline recommendation/s and rationale/s. Third, the adult recommendations and rationales were reviewed by a wide array of nephrologists, palliative care physicians, members of the Kidney End-of-Life Coalition, representatives from the American Society of Nephrology (ASN), American Nephrology Nurses Association, American Association of Kidney Patients, and National Renal Administrators Association, and a health economist. This peer review was done to identify any seminal research evidence that was missed in the literature search and any major omissions in recommendations and rationales. Peer reviewers included persons selected by the Renal Physicians Association (RPA) Quality, Safety, and Accountability Committee and nominated by stakeholder organizations. Volunteers from the nephrology community also reviewed the revision (see Section 8: Acknowledgments in the full version of the current guideline).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The rationales for each recommendation are supported by multiple references. The level of evidence is given in the original guideline document for each recommendation and rationale.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Shared decision-making is the recognized preferred model for medical decision-making because it addresses the ethical need to fully inform patients about the risks and benefits of treatments, as well as the need to ensure that patients' values and preferences play a prominent role.

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- The recommendations are not mandatory, but rather flexible guides that warrant tailoring to a particular patient, provider, and geographic circumstances. They allow the renal care team to use discretion as they are applied to individual patients. They are intended for use by providers and patients (and their families or advisors) in the United States of America and its trust territories to aid in dialysis decision-making. They are not intended for use by regulatory agencies for reimbursement or other decisions.
- Decisions to either withhold or withdraw dialysis are complex and dependent upon circumstances unique to individual patients and their
 providers. Although these recommendations are meant to aid in dialysis decision-making, they do not cover every possible contingency.
 Further, the guideline recommendations do not cover the technical management of patients receiving dialysis nor the selection of patients for

renal transplantation, topics which were previously addressed by the Renal Physicians Association (RPA), the National Kidney Foundation, and the American Society of Transplantation.

Implementation of the Guideline

Description of Implementation Strategy

Dissemination and Educational Initiatives

A first step in Guideline implementation is dissemination and education. The Working Group recommends that the Guideline document be disseminated throughout the End-Stage Renal Disease (ESRD) Networks, as well as to individual providers. They also recommended incorporation of the Guideline into nephrology and critical care fellowship training programs and continuing education workshops for practicing renal care professionals. ESRD Networks, professional organizations, and/or providers may use the guidelines to develop patient education materials. Training programs and workshops should provide opportunities for participants to develop and practice skills necessary for implementing the guidelines, such as skills in advance care planning, palliative care, and communication.

Local Implementation

Clinical practice guidelines are successful only to the extent that they improve patient care and outcomes. The limited data available suggest substantial variation among dialysis facilities with regard to advance care planning, completion of advance directives, and provider/patient (family or legal agent) communication regarding treatment options (including the right to refuse dialysis). One of the fundamental principles of Quality Improvement (QI) is that opportunities for improvement exist whenever there is variability in process and outcomes. Chronic kidney disease clinics, dialysis facilities and their patients could benefit from QI activities that seek to increase communication and shared decision-making between providers and patients or their legal agents regarding treatment and end-of-life decisions.

Quality improvement consists of a cycle of identifying areas in need of improvement, setting achievable goals, targeting activities to achieve these goals, and remeasuring performance. Choosing reliable, specific, valid, reproducible, and interpretable quality indicators will help insure successful implementation and desired improvements in care. Under the 2008 Conditions for Coverage, dialysis facilities are required to have a Quality Assessment and Performance Improvement (QAPI) program.

With these factors in mind, potential quality indicators derived from this Guideline are suggested below to assist local facilities in their QAPI efforts. Depending upon current local practices and available resources, individual facilities are encouraged to consider selecting one or more of the following areas for QAPI activities:

- Increase number of patients with advance care plans in place.
- Increase number of patients who have a designated legal decision-maker in the event of incapacity.
- Decrease number of patients reporting pain.
- Increase number of patients with symptom assessments done.
- Increase number of patients for whom nephrology clinicians have answered the "surprise" question.
- Increase number of terminally ill patients who are referred to hospice.

Suggestions and examples of some tools (e.g., methods for assessing decision-making capacity) that might be used to implement these recommendations are provided in the Toolkit in the full version of the current guideline (see also "Availability of Companion Documents").

Implementation Tools

Audit Criteria/Indicators

Clinical Algorithm

Quick Reference Guides/Physician Guides

Tool Kits

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

End of Life Care

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Guideline recommendations and their rationales for the treatment of adult patients. In: Renal Physicians Association (RPA). Shared decision-making in the appropriate initiation of withdrawal from dialysis. 2nd ed. Rockville (MD): Renal Physicians Association (RPA); 2010 Oct. p. 39-92. [370 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2000 Jan (revised 2010 Oct; reaffirmed 2013 Dec)

Guideline Developer(s)

Renal Physicians Association - Medical Specialty Society

Source(s) of Funding

Renal Physicians Association (RPA)

Guideline Committee

Renal Physicians Association Clinical Practice Guideline Revision Working Group

Composition of Group That Authored the Guideline

2010 Guideline

RPA Quality, Safety, and Accountability Committee Chair: Paul M. Palevsky, MD

RPA Clinical Practice Guideline Revision Working Group Chair: Alvin H. Moss, MD; West Virginia University School of Medicine, Morgantown, WV

For a complete list of literature review workgroup members and external reviewers, refer to Section 8 of the full version of the current guideline.

2013 Reaffirmation

Chairs or Workgroup Chairs for the Kidney Disease: Improving Global Outcomes(KDIGO) international conference: Sara Davison, MD, Conference Co-Chair, Symptom Work Group Co-chair (Canada)*; Greg Obrador, MD, Conference Co-Chair, Advanced Planning Work Group Co-â€Chair (Mexico); Brennan Frank, MD, Symptom Work Group Co-Chair (Australia); Michael Germain, MD, Prognosis Work Group Coâ€Chair (United States)*; Alvin Moss, MD, Prognosis Work Group Co-Chair (United States)*; Edwina Brown, MD, Initiation, Withholding, and Withdrawal of Dialysis Work Group Co-Chair (United Kingdom); Vivekanand Jha, MD, Initiation, Withholding, and Withdrawal Of Dialysis Work Group Co-Chair (India); Fliss Murtagh, Conservative Care Work Group Co-â€Chair (United Kingdom); Saraladevi Naicker, MD, Conservative Care Work Group Co-Chair (South Africa); Donal O'Donoghue, MD, Advanced Planning Work Group Co-Chair (United Kingdom); Jean L. Holley, MD, Advanced Planning Co-Chair (United States)*

*Chair or co-chair of RPA workgroup that developed the 2010 RPA clinical practice guideline

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Endorser(s)

American Academy of Hospice and Palliative Medicine - Professional Association

American Academy of Pediatrics - Medical Specialty Society

American Association of Critical-Care Nurses - Professional Association

American Association of Kidney Patients, Inc. - Disease Specific Society

American College of Nurse Practitioners - Medical Specialty Society

American Geriatrics Society - Medical Specialty Society

American Society of Pediatric Nephrology - Professional Association

Center to Advance Palliative Care - Professional Association

Forum of End-Stage Renal Disease Networks - Nonprofit Organization

Kidney End-of-Life Coalition - Professional Association

National Hospice and Palliative Care Organization - Nonprofit Organization

National Renal Administrators Association - Professional Association

Society of Critical Care Medicine - Professional Association

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Society of Nephrology, Renal Physicians Association. Clinical practice guideline on shared decision-making in the appropriate initiation of and withdrawal from dialysis. Washington (DC): Renal Physicians Association; 2000 Jan. 124 p. [302 references]

Galla JH. Clinical practice guideline on shared decision-making in the appropriate initiation of and withdrawal from dialysis. Renal Physicians Association and the American Society of Nephrology. J Am Soc Nephrol 2000 Jul;11(7):1340-2. [302 references]

The Renal Physicians Association reaffirmed the currency of this guideline in 2013.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Not available at this time.

Print copies: Available for purchase from the Renal Physicians Association, 1700 Rockville Pike, Suite 220, Rockville, MD 20852; e-mail, rpa@renalmd.org; telephone, (301) 468-3515; fax, (301) 468-3511, or from the Renal Physicians Association (RPA) Web site

Availability of Companion Documents

The following are available:

| • | Shared decision-making in the appropriate initiation of and withdrawal from dialysis. Recommendation summary. Rockville (MD): Renal |
|-------|---|
| | Physicians Association (RPA); 2010 Oct. 12 p. Electronic copies: Available in Portable Document Format (PDF) from the RPA Web site |
| | |
| • | Shared decision-making in the appropriate initiation of and withdrawal from dialysis. Toolkit. Rockville (MD): Renal Physicians Association |
| | (RPA); 2010 Oct. 37 p. Electronic copies: Available in PDF from the RPA Web site |
| In ad | dition, clinical performance measures on end stage renal disease (ESRD) and diabetes are available from the RPA Web site |
| | |

Patient Resources

None available

NGC Status

This summary was completed by ECRI on March 8, 2000. The information was verified by the guideline developer on March 10, 2000. This summary was updated by ECRI Institute on January 7, 2011. The updated information was verified by the guideline developer on February 4, 2011. The currency of the guideline was reaffirmed by the developer in 2013 and this summary was updated by ECRI Institute on October 2, 2015.

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